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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,827	01/15/2004	Michael R. Rosen	13533/48003	5518

26646 7590 10/17/2006

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EXAMINER

SINGH, ANOOP KUMAR

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/757,827

Applicant(s)

ROSEN ET AL.

Examiner

Anoop Singh

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 56.
Claim(s) rejected: 20, 49-51, 56, 57 and 59.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.


AUG 31

Continuation of 3: The amendments to claims 49, 51, 56-57 and newly added claim 65, describing site-specifically introducing the composition into syncytial struture or heart require new search and consideration. The site specific adminstration constitute new limitations, as said method were not recited in any of the previous claims. In additon, amendment to claim 56 also raises new rejection under U.S.C 112 paragraph 2.

Continuation of 11: The Examiner maintains the rejection of claims 20, 49-51, 56-57and 59 under 35 USC first paragraph, for reasons of record. To the extent arguments apply to the pending claims, Applicant arguments filed on 9/28/2006 have been fully considered but they are not fully persuasive. Applicants rebut the rejection of the claims under 35 USC 112, in the reply filed 9/28/2006, citing support in the specification for the amended claims. Applicants arguments based on the proposed amendments are not persuasive, because the claim amendments have not been entered and require new consideration and search. In addition, as stated in previous office action limitation of delivery of modified hMSC to free wall myocardium is not an optimal site of contraction. Although catheter approaches to insert pace maker gene have more ordered and normal activation and contraction. However, it is also noted that Applicants in post filing art describe that this approach was not available to hMSC transplant due to problem associated with cell size and potential of injury to the cell (Circ Res. 2004 Apr 16;94(7):952-9). The cited art clearly suggest that administering MSC by catheter was mere a hypothesis since extent of cell injury and potential of administering MSC by catheter was not available even after filing of instant application as stated in previous office action. Furthermore, applicants amendment that recites the limitation "sufficient" raises issue that require consideration of by what standard expression is sufficient to induce ion channel. Applicants argument that composition of claim 20 is useful in studying membrane properties of membrane potential of adult heart cell is not fully persuasive since claim 20 as recited comprises a mesenchymal stem cell incorporated with a nucleic acid which encodes a HCN2 ion channel in an amount sufficient to create ion channel in the cell. The specification contemplated to study the membrane properties of adult heart cells. Since claim 20 requires HCN2 in amount sufficient to create ion channel in the cell clearly suggests that composition is intended for inducing pacemaker activity and not for studying the coupling of adult and stem cell as argued by the applicants.

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